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Dow Jones Business News

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HEADLINE: UPDATE: Lilly Denies Report Of Zyprexa Wrong-doing

BODY:

By Val Brickates Kennedy

BOSTON (Dow Jones) - Eli Lilly & Co. vehemently defended itself on Monday against allegations raised in a recent New York Times story that said the drugmaker had inappropriately promoted its anti-psychotic medication Zyprexa.

In a statement on Monday, Lilly (LLY) maintained that it has not promoted Zyprexa, a treatment for schizophrenia and bipolar disorder, for "off-label" use, an industry term that means using a drug to treat a condition other than those for which it has been approved by the Food and Drug Administration.

While off-label use of drugs is not only legal but commonly practiced in the medical community, federal law prohibits drug companies from promoting their drugs for purposes that have not been approved.

On Monday, the Times said that leaked marketing documents showed that Lilly promoted Zyprexa to primary care physicians for such unapproved conditions as dementia in the elderly. Zyprexa carries a warning that it should not be used in older patients with dementia.

"At Lilly, we do not engage in off-label promotion - as alleged in The Times article," Dr. Steven Paul, Lilly's executive vice president for science and technology, said in a statement on Monday. "Lilly is committed to the highest ethical standards and to promoting our medications only for approved uses."

Lilly also defended promoting the drug to non-specialists, asserting that about half of patients suffering from serious mental illnesses either cannot or choose not to access psychiatric care, relying instead on their primary care physician.

The Times said the Lilly documents were provided by attorney James Gottstein, who represents mentally-ill patients. He recently sued the state of Alaska for trying to compel patients to take psychiatric medications against their will.

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Lilly has been in embroiled in long-standing litigation with Zyprexa users who claim the drug can trigger obesity and diabetes. Gottstein had subpoenaed the documents from a party involved in that litigation.

On Monday, Lilly asserted that the documents were released "illegally" and that they did not accurately portray Lilly's marketing behavior.

"The Times failed to mention that these leaked documents are a tiny fraction of the more than 11 million pages of documents provided by Lilly as part of the litigation process," the company said in a statement. "They do not accurately portray Lilly's conduct."

In 2005, Lilly agreed to pay \$750 million to settle suits filed by 8,000 former users of Zyprexa, with thousands of cases still pending, according to the Times.

Approved in 1996, Zyprexa is Lilly's best-selling drug, garnering 2005 sales of \$4.2 billion. The drug has been used by almost 20 million people worldwide, according to Lilly.

In related news, Lilly also announced Monday that it has raised its bid for partner Icos Corp. (ICOS) from \$32 a share to \$34 a share, a transaction now valued at approximately \$2.3 billion. Icos and Lilly co-market the erectile dysfunction drug Cialis. [12-18-06 1641ET]

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